UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,316	05/24/2001	Zongxuan Jin	100967-00011	1362

7590 03/09/2005

ARENT FOX KINTNER
POLTKIN & KAHN, PLLC
Suite 600
1050 Connecticut Avenue, N.W.
Washington, DC 20036-5339

EXAMINER	
JAGOE, DONNA A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/863,316
Filing Date: May 24, 2001
Appellant(s): JIN ET AL.

David T. Nikaido
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 24 October 2003.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 5-12 stand or fall together.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

6,165,982	YAMADA et al.	12-2000

(10) Grounds of Rejection

New Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibition of skin cancer in a mouse with a shaved back by chemically inducing cancer with 7, 12-dimethylbenzen[I]anthracene (DMBA) and 12-o-tetradecanoyl-phorbol13-acetate (TPA), it does not reasonably provide enablement for inhibiting skin cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary. All of the **Wands factors** have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: Claim 10 is drawn to a method of inhibiting **skin cancer** in a mammal with an effective amount of sericin. The nature of the

invention is extremely complex in that it encompasses the actual inhibition of skin cancer such that the subject treated with sericin does not contract skin cancer.

Breath of the Claims: The complex of nature of the claim is greatly exacerbated by breath of the claim. The claims encompass inhibition of skin cancer in mammals which have potentially many different causes such as heredity (familial history of skin cancer, fair skin individuals, European heritage), environment such as UV exposure, multiple nevi or atypical moles, exposure to coal and arsenic compounds, elevation (UV light is stronger as elevation increases because thinner atmosphere at higher altitude cannot filter UV as effectively as it does at sea level), latitude (the rays of the sun are strongest near the equator), repeated exposure to x-rays, and scars from disease and burns. Each of these defects may or may not be addressed by the administration sericin to inhibit skin cancer.

Guidance of the Specification: The guidance given by the specification as to how one would administer sericin to a mammal in order to actually inhibit skin cancer is minimal. All of the guidance provided by the specification is directed towards a working example of mice with shaved backs, wherein the cancer initiator DMBA is applied, and the cancer promoter TPA is applied to the skin on their backs to induce a cancer. One group was treated with topical sericin in addition to the cancer promoting agents.

Working Examples: All of the working examples provided by the specification are directed toward the inhibition of a cancer caused by DMBA and TPA.

State of the Art: While the state of the art is relatively high with regard to inhibition of skin cancer for specific causes such as UV exposure, the state of the art with regard to inhibition of skin cancer broadly is underdeveloped. In particular, there do not appear to be any examples or teachings in the prior art wherein a compound similar to the claimed compounds was administered to a subject to inhibit skin cancer caused by exposure to x-rays.

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to the actual inhibition of skin cancer caused by UV exposure or heredity or exposure to x-rays or skin that has scars or burns or chemicals other than DMBA and TPA makes practicing the claimed invention unpredictable in terms of inhibition of skin cancer in general.

The amount of Experimentation Necessary: In order to practice claimed invention, one of skilled in the art would have to first envision a cause of the skin cancer, then a combination of appropriate pharmaceutical carrier, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system and test the combination in the model system to determine whether or not the combination is effective for inhibition of skin cancer. If unsuccessful, which is likely, given the lack of significant guidance from the specification or prior art with regard to inhibition of skin cancer with sericin, one of skill in the art would have to then either envision a modification of the composition dosage, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of the

above, and test the system again. If again unsuccessful, which is likely given the lack of significant guidance from the specification of prior art regarding inhibition of skin cancer in general, the entire, unpredictable process would have to be repeated until successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention to inhibit the development of skin cancer in a mammal by administration of sericin.

Therefore, a method of inhibiting skin cancer by administering sericin is not considered to be enabled by the instant specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamada et al. U.S. Patent No. 6,165,982 A.

The claims are drawn to a method of inhibiting skin cancer in a mammal comprising administering a composition comprising sericin or a hydrolysis product of sericin wherein the average molecular weight of sericin is from 5,000 to 100,000 and the composition is administered orally, intraperitoneally, IV and topically.

Yamada et al. teach that diseases such as cancer may be at least partly caused from the lipid peroxide produced and accumulated in vivo. In order to solve such problems antioxidants have been utilized (column 1, lines 15-33). Further, Yamada et al. teach that sericin is an antioxidant.

It does not teach the sericin to be utilized as a skin cancer preventative agent.

It would have been obvious to employ sericin, a known antioxidant, to inhibit a skin cancer since it is well known by one of ordinary skill in the art that antioxidants are effective in for inhibiting skin cancer. Motivation to employ the antioxidant comes from the teachings of Yamada et al. that cancer may be at least partly caused from the lipid peroxide produced and accumulated and that antioxidants have been used to solve such problems and further that sericin is a strong antioxidant.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

No claims are allowed.

(11) Response to Argument

Regarding the 35 U.S.C. §112, first paragraph rejection, applicant asserts that the specification is not required to teach each and every detail of the invention or to be a production specification. With regard to the conditions of experimentation, the use of eight-week-old mice is insufficient to establish a generic concept. The claims are not limited to the specific action caused by the specific cancer promoters DMBA and TPA. The data is not statistically significant to scientifically show that the result obtained accrues from the method used. There is no correlation made in the specification between the effects on 8 week old mice with shaved backs and mammals in general.

Regarding the 35 U.S.C. §103(a) rejection, applicant asserts that Yamada et al disclose the use of sericin as antioxidants and tyrosinase inhibitors, used to prevent discoloration in foods and to prevent blotching of skin color caused by melanin formation. Applicant fails to point out, as in the rejection in the paper mailed 20 November 2002, that Yamada identifies maladies, such as cancer, that may be at least partly caused from lipid peroxide produced and accumulated in vivo. In order to solve such problems, anti-oxidants have been extracted from natural products or chemically synthesized (column 1, lines 15-44). Further, Yamada et al. teaches a composition comprising sericin, having "high antioxidizing activity and high inhibiting action on tyrosinase activity". In this case, the reference identifies the common problem of cancer, at least partly caused by tyrosinase activity and lipid peroxides accumulated in vivo, and since the reference gives a specific example of a single critical parameter,

antioxidant activity to combat lipid peroxides and tyrosinase activity inhibitors, thus inhibiting cancer, and provides explicit guidance by employing sericin, having "high antioxidizing activity" and a "tyrosinase activity inhibitor", it is therefore reasonable to conclude that the strength of correlation gives rise to reasonable expectation of success from combining them.

Further, the amount administered (0.1-50% by weight) provided in the instant specification appears to overlap and encompass the amount administered in Yamada et al., 0.1-50% by weight (column 4, lines 29-32). The molecular weight recited overlaps with the molecular weight of the sericin in Yamada et al. (see column 6, line7 and line 23). Yamada et al. teach the sericin is employed in compositions for external use and for oral use (column 4, lines 25-51).

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Donna Jagoe
Patent Examiner
Art Unit 1614

dj
March 7, 2005

Conferees

THURMAN K. PAGE, M.A., J.D.
SUPERVISORY PATENT EXAMINER

REBECCA COOK
PRIMARY EXAMINER
GROUP 1200/600

ARENT FOX KINTNER
POLTKIN & KAHN, PLLC
Suite 600
1050 Connecticut Avenue, N.W.
Washington, DC 20036-5339